REMARKS

Claims 15-21 have been rejected under 35 U.S.C. §251 as being an improper recapture of broadened claimed subject matter surrendered in the application for the patent upon which the present reissue is based.

More particularly, the Examiner states:

> A broadening aspect is present in the reissue which was not present in the application for patent. The record of the application for the patent shows that the broadening aspect (in the reissue) relates to subject matter that applicant previously surrendered during the prosecution of the application. Accordingly, the narrow scope of the claims in the patent was not an error within the meaning of 35 U.S.C. 251, and the broader scope surrendered in the application for the patent cannot be recaptured by the filing of the present reissue application. During the original prosecution of applicant's patent (Patent No. 5,824,046), originally filed claims 1-23 were rejected by the examiner in the Office Action mailed April 17, 1997, as being unpatentable over Myers et al. (WO 95/05132) in view of Hubis (4,478,665) under 35 U.S.C. 103(a).

Claim 1 as originally filed in the application however, reads as follows:

> A composite intraluminal device comprising:
>
> an elongate radially expandable tubular stent having an interior luminal surface and an opposed exterior surface extending along a longitudinal stent axis; and
>
> a stent cover positioned about the stent and which is formed of unsintered ePTFE which is expandable upon said radial expansion of said stent.

The following limitation was added to claim 1:

> wherein said stent covering includes an elongate segment of said unsintered ePTFE having an original longitudinal expanse, said segment being expanded in a transverse direction so as to reduce said original longitudinal expanse, said segment being positioned generally transverse to said longitudinal stent axis,

and being expandable longitudinally upon said radial expansion of said stent to return said expanded segment to said original longitudinal expanse to thereby control said radial expansion of said stent.

Applicant acknowledges that a limitation which was added during prosecution of the issued patent has been omitted from the reissue claims filed for the present application. In comparing the new reissue claims with the claims originally filed, however, it is evident that the reissue claims filed are more narrow than the originally filed, unamended claims.

The newly filed reissue claims are therefore not an attempt to recapture subject matter surrendered during prosecution of the original patent. The newly filed reissue claims are, in fact, a different limitation from the amended claims of the issued patent. The limitation added also limits the scope of the stent cover element from the originally filed claims. Applicant feels that the previous limitation entered in the Amendment was not appropriate in view of the prior art. The presently filed reissue claims include a limitation which is more appropriate in view of the prior art.

The recapture rule bars the patentee from acquiring, through reissue, claims that are of the same or of broader scope than those claims that were canceled [or amended] from the original application. On the other hand, the patentee is free to acquire, through reissue, claims that are narrower in scope than the canceled [originally filed] claims. If the reissue claims are narrower than the canceled claims, yet broader than the original [surrendered] patent claims, reissue must be sought within two years after the grant of the original patent. *Ball Corporation v. United States*, 221 USPQ 289.

Still further, the reissue claim does not fall within the scope of a doctrine of recapture if the reissue claim is materially different from the abandoned claim. There are several tests which address the idea of a "material difference". In general, a reissue claim is not subject to the doctrine of recapture if it is more restrictive in at least one significant aspect than the

canceled claim. *In re Richman*, 161 USPQ 359. A material difference may even be found where the reissue claim differs only in more precisely fingerprinting the subject matter. *In re Wadlinger*, 181 USPQ 826. The present claims are more restrictive in a certain aspect while broader in a different aspect. In short, the claims limit the invention in a more appropriate manner in view of the prior art. The claims are in no way an attempt to recapture subject matter which was surrendered.

The present reissue claims as filed, while broader in scope in some respects to the claims of the surrendered patent, are not more broad than the claims originally filed in the application of the parent case. The claims are therefore proper as they do not attempt to recapture subject matter which was surrendered, but rather attempt to limit the originally filed claims in a more appropriate manner in view of the prior art. The rejection is therefore respectfully traversed.

Rejections under 35 U.S.C. §103(a)

The Examiner has also rejected claims 15-21 under 35 U.S.C. §103(a) as being unpatentable over Myers et al. (WO 95/05132) in view of Hubis (U.S. Patent No. 4,478,665). More specifically, the Examiner states:

> Myers et al. show stent 10 and stent cover 20 formed of ePTFE having a longitudinal expanse and a transverse expanse which is expandable along said transverse expanse upon radial expansion of stent. Myers et al. fail to show the ePTFE as being unsintered. Hubis teaches that ePTFE articles such as films and tubes used in the medical field may be unsintered rather than sintered (col. 1, lines 20-30 and col. 3, lines 45-46). This results in the self-evident advantage of not having to expand the time, energy and money involved in the sintering process. It would have been obvious to use unsintered ePTFE as the material for the Myers stent cover 20 so that it too could enjoy this advantage.

Myers discloses an elongate stent having a luminal cover and/or an exterior cover formed of a sheet of expanded polytetrafluoroethylene (ePTFE). The sheet of ePTFE may

include uniaxially oriented fibrils which thereby define the longitudinal orientation of the sheet. Myers teaches that the sheet may be applied to the stent so that the fibrils orient transversely to the longitudinal axis of the stent, i.e., circumferentially around the stent. After the cover is applied to the stent, the diameter of the stent may be reduced.

Hubis discloses the use of unsintered ePTFE in the forms of tubes, rods, and sheets for medical purposes.

The present invention recites an elongate stent that is covered by an elongate sheet of unsintered ePTFE. Prior to placement over the stent, the sheet is expanded in its transverse direction, which results in the sheet decreasing in length in its longitudinal direction. The transversely expanded sheet is then applied to the stent so that the transverse direction of the sheet aligns with the longitudinal axis of the stent. The longitudinal dimension of the sheet thereby extends circumferentially around the stent. The present invention provides a covered stent which may be radially expanded to a circumference approaching, but not exceeding, the original length of the sheet of unsintered ePTFE as longitudinal expansion of the sheet is limited to its original length. The unsintered ePTFE cover of the present invention thereby defines a limit for radially expanding the covered stent beyond the diameter of the stent when the cover is first applied.

Myers provides, by contrast, a stent/graft where the ePTFE is placed on the stent when the stent is in an expanded configuration. The stent/graft of Myers is then radially reduced for insertion into a patient. Because the ePTFE cover was applied to the stent in its radially expanded condition, slack forms in the cover when the stent is radially reduced. The stent is then radially expanded at its implantation site returning to its original diameter. There is no expansion of the ePTFE cover in Myers stent/graft as it simply returns to its original state.

The present invention as claimed provides for an ePTFE cover which is, "expandable along said transverse expanse from said applied transverse expanse on radial expansion of said stent." Myers does not provide for an expandable cover. Myers cover simply returns to its original state.

Hubis similarly does not provide for such an expandable cover. The combination of Myers and Hubis, therefore, does not disclose, teach or suggest the presently claimed invention. This expandable element is absent from both Myers and Hubis, and the combination thereof simply does not disclose, teach or suggest the presently claimed invention. Withdrawal of the rejection under 35 U.S.C. §103(a) in view of Myers in further view of Hubis is therefore respectfully requested.

Rejections under 35 U.S.C. §102(e)

The Examiner has rejected claims 15-17 and 21 under 35 U.S.C. §102(e) as being anticipated by Banas et al. (U.S. Patent No. 5,749,880). More particularly, the Examiner states:

> Banas et al. show a stent 10 and stent cover 26 formed of unsintered ePTFE (column 13, lines 34-41). Although the stent cover 26 is later sintered (column 13, lines 56-57), the Banas et al. stent and stent cover prior to this sintering meet the limitations of the claims.

Claims 18-20 have also been rejected under 35 U.S.C. §103(a) as being unpatentable over Banas. Applicants will address both rejections together.

Banas teaches the use of extruded tubes. As is known in the art, polytetrafluoroethylene tubes are extruded by ram extrusion and stretched longitudinally to create a node-fibril structure longitudinally oriented with respect to the tube. The ePTFE cover of the present invention is formed from an ePTFE sheet, and is claimed as such by

indicating that the cover has a seam with overlapping edges. The use of a sheet to form a stent cover provides for a more efficient and controlled radial expansion of the prosthesis.

Banas, et al. disclose an implantable ePTFE stent/graft in which the ePTFE is assembled to the stent providing an encapsulated stent/graft. The ePTFE is applied when the stent is in a radially compressed configuration, and the node and fibril microstructure of the ePTFE is radially deformed during radial expansion of the stent/graft (see column 4, lines 41-45). The presently claimed application however provides for a stent cover formed from a sheet with a longitudinal expanse, a transverse expanse in the ePTFE cover wherein said ePTFE is expandable along said transverse expanse from said applied transverse expanse upon radial expansion of said stent. The ePTFE cover of the present invention provides for radial expansion without deformation. Such radial expansion is not shown in Banas, as the resultant ePTFE vascular graft of Banas may only expand by radially deforming the node-fibril structure of the ePTFE.

Banas, therefore, does not anticipate the present invention. Claims 18-20 are further not disclosed, taught, or suggested by Banas in combination with the known prior art. Withdrawal and reconsideration are therefore respectfully requested.

As none of the references disclose, teach or suggest the presently claimed invention, and in view of the remarks set forth above, Applicants believe that the claims are now in condition for allowance. Favorable action thereon is respectfully requested.

Should the Examiner have any questions with respect to this application, please contact the undersigned counsel.

Respectfully submitted,

Mark E. Baron
Registration No. 46,150
Attorney for Applicant(s)

HOFFMANN & BARON, LLP
6900 Jericho Turnpike
Syosset, NY 11791
(973) 331-1700

VERSION OF AMENDMENT WITH MARKINGS SHOWING CHANGES

IN THE CLAIMS:

15. (Amended) A composite intraluminal device comprising:

an elongate radially expandable tubular stent having an interior luminal surface and an opposed exterior surface extending along a longitudinal stent axis; and

an elongate stent cover applied longitudinally about the stent and which is formed of unsintered ePTFE having a longitudinal expanse and a transverse expanse as applied to said stent and which is expandable along said transverse expanse from said applied transverse expanse upon radial expansion of said stent, said stent cover having a seam formed by overlapping edges.